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Appendix C: Data management and data monitoring plan

Data Management Plan

Assessments will be completed for scoring at a later stage (from video footage). Videos will be edited as required by either the principal investigator or a therapy assistant to remove extraneous footage prior to the Assessment of Motor and Process Skills and Performance Quality Rating Scale scoring.

Coded scoring sheets will be allocated to raters by the therapy assistant. Each blind therapist will independently rate videos presented in a random order. To minimize bias related to knowledge of previous scoring, a separate form will be used for each video rating session; raters will not have access to previous scores and no discussions will take place between raters regarding scoring of study participants.

Scoring sheets will be returned to the therapy assistant who will (a) check completion and accuracy of score calculation, (b) scan to a research computer file, and (c) enter scores into the study database.

All participants will be allocated a study number that will be used on all paper and electronic records. Personal identifying information will be kept securely and separately along with other study records including consent forms and letters. Anonymized data will be entered into Excel and SPSS and will be stored as encrypted files on a password-protected laptop computer and backed up daily. Access to the anonymized data will be limited to the study principal investigator and immediate members of the study team.

Moving images acquired as part of this study will be stored in the clinical image archive where there is a specific folder for this study with access restricted to only the research team. There is a daily back up from the National Hospital Service Trust’s information technology service.

All digital and paper data will be stored for a period of 5 years from the end of the study. All data storage will follow local Trust guidelines and the Data Protection Act.

Study Management

The study is led by the principal investigator (HG) with co-investigators (RB, VC, HP, JPL) providing expertise in clinical trials, statistics, and clinical management. For a feasibility trial such as this, a formal data monitoring committee was considered unnecessary; however, management of data quality and procedures for reporting any adverse events was established within the management group.

There are no plans for an independent audit initiated by the investigators; however, the study may be subject to institutional audit at any time.

Adverse Events

If significant or adverse events occur, parents will be encouraged to have the child reviewed by a medical practitioner. Any adverse event assessed as being possible, probably, or definitely related to the intervention will be recorded. These records will be reviewed by the principal investigator and research team throughout the trial.

Data Monitoring Plan

A data monitoring committee was not required.

Consent and Assent

Written informed consent will be gathered from the child's parents or legal guardian (and the young person if 16 to 18), and assent will be sought from children and young people. A minimum of 24 hours will typically be provided to review the study information pack. However, the Evelina Children's Hospital is a tertiary regional service and patients may be seen infrequently. Where the next routine appointment is more than 3 months away, families may be approached to consent on the day of a clinical visit as this will reduce inconvenience incurred by participants. This timeline is deemed acceptable given the majority of subjects will already be familiar with the assessment process under the complex motor disorders team.

All participants will be assured that participation in the study is voluntary and that they are free to withdraw at any time without impacting the care that they receive and without providing a reason for withdrawal. This right to withdraw will be stated clearly on the invitation letter, information sheet, and consent form and will be reinforced verbally prior to beginning the research assessment.

Confidentiality

The principal investigator will act as custodian of the data. All data storage will follow local Trust guidelines and managed in accordance with the Data Protection Act 1998, NHS Caldicott Guardian, The Research Governance Framework for Health and Social Care and Research Ethics Committee Approval.

Confidentiality will be maintained by allocating participants with a unique study reference number. Personal identifying information (e.g., response forms, participant contact details, signed consent forms) will be kept securely and separately along with other study records including a record of allocated unique study reference numbers.

Moving images, scoring sheets, and anonymized data entered into Excel and SPSS will be stored within password-protected research folders. Access to data will be limited to the principal investigator, while moving images will be accessible by members of the research team for the purposes of rating.

Data will be anonymized for any future publications relating to this study.

Access to Data

The principal investigator will ensure that the trial is conducted in compliance with the principles of the Declaration of Helsinki (1996) and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework, Trust and Research Office policies and procedures and any subsequent amendments.

The principal investigator will act as custodian of the data. Participants and researchers will not receive additional payment for involvement in this study. Following completion of this study data, the intention will be to disseminate the findings of the study through peer-reviewed articles in scientific journals, presentations at conferences, and internally within our institution. All published data will be anonymized; no personal data will be used in any dissemination.

Ancillary and Post-Trial Care

Everyone will receive treatment. After completion of the study, participants return to receive usual care.